

REMARKS

Claims 1-3, 5-8 and 10-19 are currently under consideration in this application. Claims 1, 5 and 15 are currently amended. Claim 4 was previously canceled and claims 9 and 20-28 were previously withdrawn.

As stated previously, selection of a mixture of biodegradable polymers where one polymer is more hydrophobic than another polymer in the mixture allows for control of the degree of the initial burst release from the microparticles. As well, the inclusion of one polymer with greater hydrophobicity allows for a longer period of sustained release of the carbamate from the microparticle (see paragraph [0030] of the application as originally filed).

Thus, claims 1 and 15 have been amended to specify that the inclusion of the mixture of first and second biodegradable polymers wherein one of the polymers is more hydrophobic than the other polymer, results in initial burst release or sustained release of the carbamate being dampened or slowed, respectively, relative to a microparticle comprising the less hydrophobic polymer and not the more hydrophobic polymer. Support for the amendment is found at least at paragraphs [0029] and [0030] of the application as filed. As well, claim 5 has been amended to refer to the biodegradable polymer.

Amendment of these claims is proper after final rejection at least because the amendments place the claims in better condition for allowance, or appeal if such action becomes necessary.

Claim Rejections 35 U.S.C. §102

Claims 1-3, 5-8, 10-13, 15-16 and 18-19 are rejected under 35 USC 102(b) as being anticipated by Roorda et al. The Office stated that the cited reference discloses the use of PGLA, polyesters and polyanhydrides in combinations and mixtures, and thus inherently anticipates the present claims. The Office stated that the relevance of Applicant's previous arguments that the cited reference does not teach a mixture wherein one polymer is more hydrophobic than the other is not clear.

Applicant points out that if the Office relies on inherent anticipation by a particular reference, the onus lies with the Office to demonstrate that the reference necessarily embodies the presently claimed invention (see 2112.IV of MPEP). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. The mere fact that a certain thing may result from a given set of circumstances is not sufficient basis for a claim of inherent anticipation.

Particularly, where the cited reference discloses a broad genus of potential applications, this is not sufficient to support a claim of inherent anticipation. Disclosure of a genus does not inherently disclose all species within that broad category. A reference that discloses a broad genus must be examined to see if a disclosure of the claimed species has been made or whether the reference merely invites further experimentation to find the species.

In the instant case, Applicant submits that recitation in Roorda et al. that "Mixtures and combinations of these [aforementioned polymers] may also be used" is recitation of a broad genus of possible combinations of a list of individual polymers. This is a genus of combinations of polymers, each chosen from the list, and includes possible combinations of only hydrophilic polymers, as well as possible combinations of polymers having equivalent hydrophobicity, both of which types of possible combinations would fall outside the scope of the present claims.

Moreover, Roorda et al. only actually describes one specific combination, that of polymers A and B (column 4 of Roorda et al.). The combination disclosed by Roorda et al. includes two polymers of equivalent hydrophobicity. That is, both polymers A and B are poly(orthoester)s, with A including a cycloalkyl group in the polymer backbone and B containing a linear alkyl group in the polymer backbone. A skilled person would consider these polymers to have the same degree of hydrophobicity.

Thus, Applicant submits that the presently claimed mixture of two polymers wherein one polymer is more hydrophobic than the other does not necessarily result when the teaching of Roorda et al. is followed. Not every combination of polymers in the list in Roorda et al. is a combination wherein one polymer is more hydrophobic than the other. Even if upon reading Roorda et al. a skilled

person may choose a mixture of two polymers where one polymer has greater hydrophobicity than the other (which is not admitted), this result does not necessarily flow from Roorda et al., as required in the case of inherent anticipation.

Furthermore, Roorda et al. gives no indication that it would be desirous to select a combination of polymers as specified in the present claims. There is no direction to a skilled person to select the polymers to have varying degrees of hydrophobicity or that there would be any advantage or reason to do so. Particularly, Roorda et al. does not disclose that by including a more hydrophobic polymer in a microparticle with a less hydrophobic polymer, the initial burst release of the active carbamate from the microparticles is dampened or that the sustained release rate of the active carbamate from the microparticles is slowed, as specified in the claims as currently amended.

This lack of specific disclosure of the presently claimed combination, together with only a specific disclosure of a combination that falls outside the present claims, means that Roorda et al. merely describes a broad genus without specific disclosure of the presently claimed species and without specifying that at least one of the initial burst release or sustained release is modulated and therefore this cited reference cannot inherently anticipate the present claims.

In view of the foregoing, Applicant submits that Roorda et al. does not inherently anticipate the present claims and therefore respectfully requests withdrawal of the §102(b) rejection based on Roorda et al.

Claim Rejections 35 U.S.C. §103

The Office rejected claims 1-3, 5-8 and 11-18 under 103(a) as obvious having regard to Roorda et al. on the basis that the cited reference discloses the use of PGLA, polyesters and polyanhydrides in combinations and mixtures, and thus the subject matter of the present claims is inherent/obvious.

Applicant respectfully disagrees that the present claims are obvious having regard to the Roorda et al. reference, for at least the following reasons.

As stated above, Applicant submits that the Roorda et al. reference does not teach or even suggest a microparticle comprising a mixture of biodegradable polymers, in which one biodegradable polymer is more hydrophobic than another biodegradable polymer in the mixture such that the mixture of polymers results in dampening of the initial burst release of carbamate or slowing of the sustained release of carbamate from the microparticles.

As stated above, Roorda et al. at most describes a broad genus of possible combinations, with disclosure of a particular species of combination that is outside of and contrary to the particular species of combination that is presently claimed. Roorda et al. does not provide any disclosure of the particular combination specified in the present claims, and furthermore the description of Roorda does not necessarily result in a combination of polymers that falls within the scope of the present claims and thus does not necessarily provide the effect on the release rates, as specified in the present claims.

The reference does not specify that the polymers in the mixture are chosen such that one polymer is more hydrophobic than another polymer. That is, the particular species taught in the present claims is not mentioned or taught in the reference, nor is there any indication that by manipulating the hydrophobicities of the combined polymers, the release rate of the carbamate from the microparticle can be controlled. Rather, Roorda et al. teaches that the release rate from the described device is primarily independent of the rate of erosion of the polymer matrix, and thus teaches away from the presently claimed invention.

That is, in the present application, the rate of erosion of the polymer matrix is determined at least in part by the dissolution rate of the polymers, and is thus a function of the hydrophobicity of the combined polymers (see paragraphs [0029] and [0030] of the application as originally filed). Roorda et al. instead discloses that the release rate is dependent on the amount of required excipient included in the device [microparticle] of Roorda et al. Thus, upon reading of Roorda et al., a skilled person would be given an example of a combination of polymers from the same class having the same hydrophobicity, and would be discouraged from adjusting the hydrophobicities and thus the dissolution rate of any combination of polymers in order to adjust the release rate of an active ingredient. Thus,

there is no motivation or direction provided in Roorda et al. for a skilled person to try adjusting the hydrophobicity of a combination of polymers or to try the presently claimed combination of polymers.

Given the lack of direction in Roorda et al., and given that selection of the particular combination as presently claimed provides the advantage of being able to adjust both the initial burst release and the sustained release of the carbamate from the microparticle, Applicant respectfully submits that the subject matter of the present claims is not inherent/obvious in light of Roorda et al.

Applicant therefore submits that the present claims are not obvious in light of the cited reference and respectfully requests withdrawal of the rejection under 35 USC 103 based on Roorda et al.

In view of the foregoing, Applicant respectfully requests withdrawal of the claim objections and rejections and favorable reconsideration of the application.

CONCLUSION

It is believed that the claims are now in condition for allowance but, if any minor issues need to be resolved before such a notice can be issued, the Examiner is requested to telephone the undersigned at the number shown below.

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